NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES of AMERICA, et al., *Ex rel.* Laurie Simpson, Plaintiff / Relator, v. BAYER CORP., et al., Defendants.	Civil Action No. 05-3895 (JLL) (JAD) **OPINION**

LINARES, District Judge.

This matter comes before the Court by way of Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., and Bayer Healthcare LLC (collectively "Bayer")'s motion to dismiss Relator Laurie Simpson ("Simpson")'s Eighth Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). (ECF No. 144). The Court has considered the parties' submissions in support of and in opposition to the instant motion and decides this matter without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons set forth below, the Court **GRANTS** Bayer's motion.

I. BACKGROUND

Simpson brings this *qui tam* action against Defendant Bayer, her former employer, under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, and similar state and local statutes. (Compl. ¶¶ 4-8, ECF No. 135). Bayer employed Simpson from April 27, 1998 until January 1, 2005. (*Id.* at ¶ 91). As an employee of Bayer, Simpson helped market one of Bayer's prescription drugs, Trasylol. (*See id.* at ¶¶ 91-96). Simpson alleges, in short, that Bayer illegally

promoted Trasylol by "engag[ing] in a campaign of concealment and disinformation concerning Trasylol's safety and efficacy that continued at least until May 2008, when Bayer recalled Trasylol from the market." (*Id.* at ¶ 9). These promotional activities, according to Simpson, violated the Food Drug and Cosmetic Act (the "FDCA")'s prohibition against "misbranding." (*Id.* at ¶ 13).

A. The FDCA's Prohibition Against Misbranding

"The FDCA regulates the manufacturing, marketing and sale of prescription drugs," and explicitly prohibits "misbranded" drugs from entering interstate commerce. *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 239-40 (3d Cir. 2012) (citations omitted). A drug is misbranded if its labeling is "false or misleading in any particular." 21 U.S.C. § 352(a). Likewise, a drug is misbranded if its "labeling, which under the statute includes all drug manufacturer promotional and advertising material, describes any intended uses for the drug not approved by the [Food and Drug Administration ("FDA")]." *Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1357 n.5 (11th Cir. 2011) (citations omitted). Thus, the FDCA "generally restricts pharmaceutical manufacturers—and all those within their chain of distribution—from promoting a drug's potential off-label uses to . . . physicians." *Id.* (citations omitted); *see also In re Schering Plough Corp.*, 678 F.3d at 240 ("[T]he FDCA's regulatory regime prohibits manufacturers from directly advertising off-label uses, such as through labeling claims or explicit statements made by sales representatives.").

B. Bayer's Alleged Misbranding of Trasylol

Simpson generally alleges that Bayer misbranded Trasylol by promoting off-label uses of the drug. (Compl. ¶¶ 134, 136-37, 143, 145, 148, 151-52, 157, 164, 166-69). The FDA approved Trasylol for administration to patients undergoing coronary artery bypass graft surgery

using a cardiopulmonary bypass pump (hereinafter "on-pump CABG surgery") to prevent excess bleeding. (*See id.* at ¶¶ 99-100, 102-03). Simpson alleges that Bayer disregarded the limited scope of the FDA's approval by promoting the use of Trasylol in: (1) valve replacement surgeries; (2) off-pump CABG surgeries; (3) surgeries involving pediatric patients; (4) surgeries involving patients on the antiplatelet drug Plavix; (5) orthopedic surgeries; and (6) liver transplant surgeries. (*Id.* at ¶¶ 146-52, 157, 164-65). She further alleges that Bayer failed to update Trasylol's label to provide relevant safety and efficacy information concerning such off-label uses. (*Id.*). These allegations are at the heart of the thirty causes of action that Bayer now moves to dismiss.[1]

C. Simpson's Causes of Action Against Bayer

The causes of action that Bayer now moves to dismiss in their entirety fall into three categories. Counts I through VI fall within the first category: FCA causes of action that allege that Bayer's misbranding of Trasylol resulted in the submission of false claims to the Government.[2] (*Id.* at ¶¶ 318-53(II)).[3] Counts VII and VIII fall within the second category: FCA causes of action that allege that Bayer's misbranding of Trasylol caused healthcare providers to submit false claims for Medicare reimbursement. (*Id.* at ¶¶ 354(II)-65(II)). Counts XIII through

[1] Bayer had also moved to dismiss Simpson's New York City False Claims Act cause of action (Count XXXV). (Def.'s Br. 23, ECF No. 141-1). On March 28, 2014, the parties stipulated to the dismissal of that cause of action pursuant to Federal Rule of Civil Procedure 41(a)(1), and, as a result, the Court dismissed it on March 31, 2014. (Stipulation & Order of Dismissal, ECF No. 146).

[2] Simpson alleges that Bayer submitted, or caused to be submitted, false claims for Trasylol to the following Government entities: (1) the Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA"); (2) the Federal Employees Health Benefits ("FEHB") Program; (3) Medicaid; (4) Medicare; (5) TRICARE; (6) the United States Department of Defense (the "DOD"); and (7) the United States Department of Veterans Affairs (the "VA"). (Compl. ¶¶ 318-353(II)).

[3] The numbering of Simpson's Complaint is incorrect. The Complaint uses the numbers 346 through 365 twice when numbering paragraphs. When this Court cites to the first instance in which a number is used for a paragraph, the Court follows that number with a (I), *e.g.*, 346(I). When this Court cites to the second instance in which a number is used for a paragraph, the Court follows that number with a (II), *e.g.*, 346(II).

XXXIV and XXXVII fall within the third and final category: state and District of Columbia false claims act causes of action.[4] (*Id.* at ¶¶ 395-537, 545-46). Notably, this Court previously dismissed these causes of action without prejudice last August. *U.S. ex rel. Simpson v. Bayer Corp.*, No. 05-3895, 2013 WL 4710587, *17 (D.N.J. Aug. 30, 2013) (Linares, J.). Bayer also moves to dismiss Simpson's remaining causes of action to the extent that they are premised on conduct predating the applicable statute of limitations. (Def.'s Br. 27-29).

D. Jurisdiction

The Court has jurisdiction over Simpson's federal FCA causes of action pursuant to 28 U.S.C. § 1331, and jurisdiction over her state false claims act cause of action pursuant to both 28 U.S.C. § 1367 and 31 U.S.C. § 3732(b).

II. LEGAL STANDARD

For a complaint to survive dismissal, it "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.*

In determining the sufficiency of a complaint, the Court must accept all well-pleaded factual allegations in the complaint as true and draw all reasonable inferences in favor of the non-moving party. *See Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008). But, "the tenet that a court must accept as true all of the allegations contained in a complaint is

[4] Simpson alleges that Bayer violated the false claims acts of twenty-two different jurisdictions: (1) California (Count XIII); (2) Delaware (Count XIV); (3) Florida (Count XV); (4) Georgia (Count XVI); (5) Hawaii (Count XVII); (6) Illinois (Count XVIII); (7) Indiana (Count XIX); (8) Louisiana (Count XX); (9) Massachusetts (Count XXI); (10) Michigan (Count XXII); (11) Montana (Count XXIII); (12) Nevada (Count XXIV); (13) New Hampshire (Count XXV); (14) New Mexico (Count XXVI); (15) New York (Counts XXVII and XXXVII); (16) Oklahoma (Count XXVIII); (17) Rhode Island (Count XXIX); (18) Tennessee (Count XXX); (19) Texas (Count XXXI); (20) Virginia (Count XXXII); (21) Wisconsin (Count XXXIII); and (22) the District of Columbia (Count XXXIV). (Compl. ¶¶ 395-537, 545-46).

inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678. Thus, legal conclusions draped in the guise of factual allegations may not benefit from the presumption of truthfulness. *Id.*; *In re Nice Sys., Ltd. Sec. Litig.*, 135 F. Supp. 2d 551, 565 (D.N.J. 2001).

Additionally, in evaluating a plaintiff's claims, generally "a court looks only to the facts alleged in the complaint and its attachments without reference to other parts of the record." *Jordan v. Fox, Rothschild, O'Brien & Frankel*, 20 F.3d 1250, 1261 (3d Cir. 1994). However, "a document integral to or explicitly relied on in the complaint may be considered without converting the motion [to dismiss] into one for summary judgment." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (internal quotation marks omitted and alteration in the original). With this framework in mind, the Court now addresses Bayer's motion to dismiss Simpson's Eighth Amended Complaint.[5]

III. DISCUSSION

As explained above, the causes of action that Bayer now moves to dismiss fall into three categories: (1) FCA causes of action premised on Bayer's misbranding of Trasylol and the resultant submission of false claims to the Government; (2) FCA causes of action premised on Bayer's misbranding of Trasylol and the resultant submission of false claims for Medicare reimbursement by healthcare providers; and (3) state and District of Columbia false claims act causes of action. The Court will now consider, in turn, whether each category survives dismissal, and will then consider the extent to which Simpson's remaining causes of action are cabined by the applicable statute of limitations.

[5] All further references to Simpson's Complaint refer to the Eighth Amended Complaint unless otherwise specified.

A. Whether Simpson's FCA Causes of Action Premised on Bayer's Misbranding of Trasylol and the Resultant Submission of False Claims to the Government Survive Dismissal

The first six counts of Simpson's Eighth Amended Complaint allege that Bayer violated sections 3729(a)(1) and (2) of the FCA.[6] (Compl. ¶¶ 318-53(II)). Simpson alleges in those counts that "Bayer misbranded Trasylol by marketing and selling the drug for off-label uses," and "by misrepresenting the drug's safety and efficacy." (*Id.* at ¶¶ 321-22, 330-31, 339-40, 348(I)-49(I), 357(I)-58(I), 347(II)-48(II)). She also alleges that since Bayer misbranded Trasylol, it "was prohibited from interstate commerce," and that, as a result, each claim for payment for Trasylol "was false or fraudulent in implying that the drug was not misbranded and was permitted in interstate commerce." (*Id.* at ¶¶ 323-24, 333-34, 341-42, 351(I)-52(I), 359(I)-60(I), 350(II)-51(II)). Bayer now moves to dismiss the first six counts of Simpson's Complaint for failure to state a claim. (Def.'s Br. 6-12).

Sections 3729(a)(1) and (2) of the FCA impose liability on any person who:

> (1) knowingly presents, or causes to be presented, [to the United States Government] a false or fraudulent claim for payment or approval; [or]
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.

31 U.S.C. § 3729(a)(1)-(2) (pre-FERA). Based on this language, the Third Circuit has concluded that a plaintiff must plead three elements to state a claim under section 3729(a)(1) of the FCA: "(1) the defendant presented or caused to be presented to an agent of the United States a claim

[6] In May 2009, Congress enacted the Fraud Enforcement and Recovery Act of 2009 ("FERA"), thereby amending the FCA and redesignating section 3729(a)(1) as section 3729(a)(1)(A) and section 3729(a)(2) as section 3729(a)(1)(B). Pub. L. No. 111-21, 123 Stat. 1617 (2009). Simpson's Complaint cites to the pre-FERA version of the FCA, which she asserts applied during the time period relevant to this action. (Compl. ¶ 31). Bayer explicitly agrees with that assertion, and cites to the pre-FERA version of the FCA in its briefs. (Def.'s Br. 1 n.1).

for payment;[7] (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004) (quotation marks and citation omitted). A plaintiff must plead the same three elements to state a claim under section 3729(a)(2) of the FCA along with a fourth element, *i.e.*, "that the defendant made or used (or caused someone else to make or use) a false record in order to cause the false claim to be actually paid or approved." *Id.* (citation omitted).

In this case, the parties dispute whether the first six counts of Simpson's Complaint adequately plead the second element—a false or fraudulent claim for payment. (*See* Def.'s Br. 7-12; Pl.'s Opp'n Br. 4-15, ECF No. 144-17; Def.'s Reply Br. 3-5, ECF No. 144-23). In resolving their dispute, the Court is guided by the Third Circuit's pronouncement that there are two categories of false or fraudulent claims under the FCA: factually false claims and legally false claims. *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011) (citing *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008)). "A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government . . . ." *Id.* Alternatively, "a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *Id.* "A legally false FCA claim is based on a 'false certification' theory of liability." *Id.* (citation omitted).

There are two "false certifications" theories of liability: the express false certification theory and the implied false certification theory. *Id.* (citation omitted). "Under the 'express false certification' theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with

[7] The FCA defines a claim in pertinent part as a "request or demand . . . for money or property that . . . is presented to an officer, employee, or agent of the United States . . . ." 31 U.S.C. § 3729(c) (pre-FERA).

the claim for payment of federal funds." *Id.* (citation omitted). On the other hand, under the implied false certification theory, an entity is liable if it "seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment." *Id.* (citation omitted).

Here, Simpson contends that the first six counts of her Complaint "are viable without reliance on a false certification theory." (Pl.'s Opp'n Br. 11). Specifically, she maintains that her "primary theory of liability . . . is based on the evident materiality of misbranding to the government, and not solely on false certification." (*Id.* at 3). However, Simpson cites to no binding Third Circuit authority explicitly recognizing the viability of such a theory of liability under the FCA,[8] and this Court is aware of none. *See Wilkins*, 539 F.3d at 305 ("There are two categories of false claims under the FCA: a factually false claim and a legally false claim."). At bottom, the first six counts of Simpson's Complaint rely on an implied false certification theory since they are predicated on Bayer's alleged violation of the FDCA. Indeed, those counts explicitly allege that each claim for payment for Trasylol was "false or fraudulent in implying that the drug was not misbranded and was permitted in interstate commerce." (Compl. ¶¶ 324, 334, 342, 352(I), 360(I), 351(II)).

To plead an implied false certification theory, "a plaintiff must show that compliance with the regulation which the defendant allegedly violated was a *condition of payment* from the Government." *Id.* at 309 (emphasis added and citations omitted); *see also Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) ("[A] claim for reimbursement made to the government is not

[8] Simpson cites to *U.S. ex rel. Dunleavy v. County of Delaware*, 123 F.3d 734 (3d Cir. 1997) *abrogated by Graham County Soil & Water Conservation District v. U.S. ex rel. Wilson*, 559 U.S. 280 (2010), for the proposition that "Bayer's concealment of the fact that Trasylol was misbranded and illegal in interstate commerce rendered those claims false." (Pl.'s Opp'n Br. 6). Simpson's reliance on *Dunleavy* is misplaced since that case dealt with the public disclosure bar, and does not suggest that Simpson's theory of FCA liability is viable. *See Dunleavy*, 123 F.3d 734.

legally false simply because the particular service furnished failed to comply with the mandates of a statute, regulation or contractual term that is only tangential to the service for which reimbursement is sought."). Whether a defendant's compliance with a statute or regulation is a "condition of payment" from the Government is distinct from whether such compliance is "material" to the Government. *See Mikes*, 274 F.3d at 697 (explaining that a condition of payment requirement is distinct from a materiality requirement); *see also Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 793 (4th Cir. 1999) ("The prerequisite standard in the false certification cases is essentially a heightened materiality requirement: the government must have conditioned payment of the claim upon certification of compliance with the provision of the statute, regulation, or contract at issue."). A defendant's compliance with a statute or regulation is a condition of payment when knowledge of the defendant's failure to comply "'might cause [the Government] to actually refuse payment.'" *Wilkins*, 659 F.3d at 309 (quoting *Conner*, 543 F.3d at 1220). In contrast, a defendant's compliance with a statute or regulation is material to the Government when the defendant's failure to comply "has a natural tendency to influence agency action or is capable of influencing agency action." *Harrison*, 176 F.3d at 785 (quotation marks and citation omitted).

Simpson argues at length that this Court should not dismiss the first six counts of her Complaint because they sufficiently allege that Bayer's compliance with the misbranding provisions of the FDCA was material to the Government. (Pl.'s Opp'n Br. 4-10). While the Court is mindful that there is some overlap between the "materiality" and "condition of payment" concepts, they are in fact distinct. Indeed, a defendant's failure to comply with a statute or regulation when submitting a claim for payment to the Government may induce the Government to act in a manner other than refusing to pay the claim. *See Wilkins*, 659 F.3d at

309 (noting that the defendant's noncompliance with Medicare marketing regulations could induce the Government to eventually bar the defendant from participating in the Medicare program, but that it did not necessarily provide the Government with a reason to refuse the defendant's requests for payment). Even if the Court were to consider Simpson's allegations pertaining to the materiality of misbranding to the government, as explained below, those allegations do not adequately plead that Bayer's compliance with the FDCA's misbranding provisions was a condition of payment from the Government. *See id.*, 659 F.3d at 307 ("[A] plaintiff must show that if the Government had been aware of the defendant's violations of the . . . laws and regulations that are the bases of [her] FCA claims, it would not have paid the defendant's claims.").

Simpson's Complaint alleges that the United States Department of Justice ("DOJ")'s "pursuit of [a number of misbranding] cases, and the resulting settlements, are evidence that the federal government deems misbranding to be a material ground for recovering federal funds expended on pharmaceuticals." (Compl. ¶ 49). It can be reasonably inferred from this allegation that the Government may eventually sue a drug manufacturer for failing to comply with the FDCA's misbranding provisions. It does not follow, however, that the Government conditions its payments for pharmaceuticals on a drug manufacturer's compliance with the FDCA's misbranding provisions. Thus, Simpson's allegation concerning the DOJ's pursuit of a number of misbranding cases does not adequately plead the existence of a condition of payment.

Simpson's allegation that the DOJ's filing of statements of interest ("SOIs") in two separate cases—(1) *U.S. ex rel. Krahling v. Merck & Co.*, No. 10-4374 (E. D. Pa.); and (2) *U.S. ex rel. Provuncher v. Angioscore, Inc.*, No. 09-12176 (D. Mass.)—evidences "[t]hat the federal government considers misbranding to be material to its decisions to pay or seek reimbursement

of payments for pharmaceuticals," (*Id.* at ¶¶ 50-51), also fails to plead the existence of a condition of payment. In *Krahling*, as Bayer notes, the DOJ challenged the defendant's legal argument that a private relator—as opposed to the Government—could not state a claim under the FCA premised on allegations of fraud or a violation of FDA regulations. No. 10-4734, ECF No. 54 (E. D. Pa. March 20, 2013). In doing so, the DOJ did not explicitly argue or suggest that the Government generally conditions its payments for drugs on a drug manufacturer's compliance with the FDCA provisions at issue here. *See id.* In *Provuncher*, the DOJ addressed a theory of fraud on the FDA that Simpson has not alleged here, and which the District Court of Massachusetts eventually dismissed. No. 09-12176, 2012 WL 3144885 (D. Mass. Aug. 3, 2012). Therefore, Simpson's allegations concerning the materiality of the FDCA's misbranding provisions to the Government do not allege the existence of a condition of payment. The Court now considers whether Simpson otherwise alleges the existence of a condition of payment in her causes of action involving payments from: (1) CHAMPVA, the FEHB Program, the DOD, TRICARE, and the VA (Counts I and II); (2) Medicaid (Counts III and IV); and (3) Medicare (Counts V and VI).

1. Whether Simpson's Complaint Alleges that CHAMPVA, the FEHB Program, the DOD, TRICARE, and the VA Conditioned Their Payments for Trasylol on Bayer's Compliance with the Misbranding Provisions of the FDCA

Counts I and II of Simpson's Complaint allege that Bayer violated the FCA by submitting, or causing others to submit, false or fraudulent claims for payment for Trasylol to CHAMPVA, the FEHB Program, the DOD, TRICARE, and the VA. (Compl. ¶¶ 318-35). Those Counts allege that such claims for payment were false or fraudulent since they implied that Bayer had complied with the misbranding provisions of the FDCA. (*See id.* at ¶¶ 324, 334). Those Counts, however, do not allege that Bayer's compliance with the misbranding provisions

was a condition of payment from any of the aforementioned federal entities. (*See id.* at ¶¶ 318-35). They provide only the conclusory statement that "[i]f the United States had known that Trasylol was misbranded and prohibited from interstate commerce, it would not have paid for it." (*Id.* at ¶¶ 325, 335). This bare legal conclusion does not adequately plead the existence of a condition of payment. *Cf. Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (noting that conclusory or bare-bones allegations do not survive a motion to dismiss). As a result, this Court dismisses Counts I and II of Simpson's Complaint without prejudice. *See Wilkins*, 659 F.3d at 311 (affirming district court's dismissal of the plaintiff's FCA cause of action because the defendant's compliance with a marketing regulation was not a condition of payment).

2. Whether Simpson's Complaint Alleges that the United States Conditioned its Medicaid Reimbursements for Trasylol on Bayer's Compliance with the Misbranding Provisions of the FDCA

Counts III and IV of Simpson's Complaint allege that Bayer violated the FCA by causing healthcare providers to submit false or fraudulent claims for Medicaid reimbursement for Trasylol to the Government. (Compl. ¶¶ 336-53(I)). Those Counts further allege that those reimbursement claims were false or fraudulent since they implied that Bayer had complied with the misbranding provisions of the FDCA. (*Id.* at ¶¶ 342, 352(I)). Simpson's Complaint elsewhere alleges that "[m]any state Medicaid Programs require health care providers to certify compliance with federal and state law," and to also acknowledge that they could be prosecuted for submitting a false claim. (*Id.* at ¶ 72; Pl.'s Opp'n Br. 12).

Based on that allegation, the Court can plausibly infer that a healthcare provider's outright refusal to provide such a certification would be met with a refusal by the Government to pay Medicaid reimbursements. But the Court cannot plausibly infer from that allegation that the Government would refuse to pay Medicaid reimbursements for Trasylol based on Bayer's

noncompliance with the misbranding provisions of the FDCA. Such an inference would be speculative at best. *Cf. Zavala v. Wal Mart Stores Inc.*, 691 F.3d 527, (3d Cir. 2012) ("Even on a motion to dismiss, we are not required to credit mere speculation."). Moreover, that the Government may prosecute a false claim has no bearing on whether one's compliance with the misbranding provisions of the FDCA is a condition of payment from the Government for Medicaid reimbursements. Accordingly, the Court dismisses counts III and IV of Simpson's Complaint without prejudice. In holding so, the Court observes that "the [FCA] was not designed for use as a blunt instrument to enforce compliance with all medical regulations—but rather only those regulations that are a precondition to payment." *Mikes*, 274 F.3d at 699.

3. Whether Simpson's Complaint Alleges that the Government Conditioned its Medicare Reimbursements for Trasylol on Bayer's Compliance with the Misbranding Provisions of the FDCA

Counts V and VI of Simpson's Complaint allege that Bayer violated the FCA by submitting, or causing others to submit, false or fraudulent claims for Medicare reimbursement for Trasylol to the Government. (Compl. ¶¶ 354(I)-53(II)). Those Counts allege that such reimbursement claims were false or fraudulent because they implied that Bayer had complied with the misbranding provisions of the FDCA. (*Id.* at ¶¶ 360(I), 351(II)). Simpson points the Court to two allegations in her Complaint, which she suggests establish that Bayer's compliance with the misbranding provisions was a condition of payment from the Government. (Pl.'s Opp'n Br. 12-13).

First, Simpson points to her allegation that "[t]o enroll in Medicare, healthcare providers and suppliers must fill out and sign an application form. Institutional providers, such as hospitals, use the CMS-855A form, physicians and non-physician practitioners use the CMS-

855I form, and all other healthcare providers use the CMS-855B form." (Compl. ¶ 53). All CMS-855 forms, according to Simpson's Complaint, require healthcare providers to certify:

> I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with *such laws, regulations, and program instructions* (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

(*Id.* (emphasis added)). Simpson suggests that this language establishes that Bayer's compliance with the misbranding provisions of the FDCA was a condition of payment from the Government. (*See* Pl.'s Opp'n Br. 12). Bayer counters that this allegation is "insufficient because Simpson does not identify any authority for the proposition that the FDA marketing rules at issue here are among the requirements on which Medicare . . . payment is conditioned." (Def.'s Reply Br. 4-5). The Court agrees. The Court is incapable of reasonably inferring that "such laws [and] regulations" in the above quoted language refers to the FDCA misbranding provisions because Simpson has not provided the Court with the broader context of that language nor has she alleged other facts that would allow the Court to infer which laws and regulations "such laws [and] regulations" includes.[9]

Second, Simpson points to her allegation that hospitals are required to file a cost report to participate in the Medicare Program. (Pl.'s Opp'n Br. 12). Hospitals allegedly certify therein that they are "familiar with the laws and regulations regarding the provision of health care

[9] When deciding a motion to dismiss, generally, "a court looks only to the facts alleged in the complaint and its attachments . . . ." *Jordan*, 20 F.3d at 1261. However, a court may also look to "a document integral to or explicitly relied on in the complaint" without converting the motion into one for summary judgment. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1426 (quotation marks and citation omitted). This exception to the general rule exists "so that [a] plaintiff cannot maintain a claim 'by extracting an isolated statement from a document and placing it in the complaint, even though if the statement were examined in the full context of the document, it would be clear that the statement [did not support the claim].'" *Mele v. Fed. Reserve Bank of N.Y.*, 359 F.3d 251, 256 n.5 (3d Cir. 2004) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1426). Here, Simpson did not attach a copy of a CMS-855 form to her Complaint, and neither party has supplied a copy in its moving papers. Since the Court does not have a copy of a CMS-855 form, the Court is unable to examine the full context of the language from the form that Simpson quotes in her Complaint.

services and that the services . . . were provided in compliance with such laws and regulations." (Compl. ¶ 64). Based on this certification, the Court cannot reasonably infer that the Government would refuse to pay Medicare reimbursements for Trasylol due to Bayer's noncompliance with the misbranding provisions of the FDCA. *Cf. Wilkins*, 659 F.3d at 309-10 ("[T]he fundamental flaw in appellants' allegations is that the amended complaint does not cite to any regulation demonstrating that a participant's compliance with Medicare marketing regulations is a condition for its receipt of payment from the Government."). Thus, the Court dismisses Counts V and VI of Simpson's Complaint without prejudice.

B. Whether Simpson's FCA Causes of Action Premised on Bayer's Misbranding of Trasylol and the Resultant Submission of False Claims for Medicare Reimbursement Survive Dismissal

Counts VII and VIII of Simpson's Complaint allege, in essence, that because Bayer falsely certified compliance with the Medicare statute, Bayer is liable under the FCA. (Compl. ¶¶ 354(II)-65(II)). A defendant falsely certifies compliance with the Medicare statute if it submits, or causes to be submitted, a claim for Medicare reimbursement of a drug when the use of that drug was not "*reasonable and necessary* for the diagnosis or treatment of illness or injury . . . ." 42 U.S.C. § 1395y(a)(1)(A) (emphasis added); *Mikes*, 274 F.3d at 700. Thus, whether Counts VII and VIII may proceed hinges on whether the Complaint alleges that the off-label uses of Trasylol that Bayer promoted were not "reasonable and necessary." *Mikes*, 274 F.3d at 700.

The Medicare statute explicitly empowers the Secretary of Health and Human Services to decide one's entitlement to Medicare benefits. 42 U.S.C. § 1395ff(a)(1)(A). In doing so, the Medicare statute authorizes the Secretary "to determine whether the numerous medical services and items covered by Medicare are 'reasonable and necessary' in particular circumstances." *Willowood of Great Barrington, Inc. v. Sebelius*, 638 F. Supp. 2d 98, 105 (D. Mass. 2009) (citing

Goodman v. Sullivan, 891 F.2d 449, 450 (2d Cir. 1989)). The Secretary sets forth such determinations in "both formal regulations and informal policy manuals." *Id.* In her Opposition Brief, Simpson cites to two such manuals, the Medicare Benefit Policy Manual (the "MBPM) and Medicare Program Integrity Manual (the "MPIM"). (Pl.'s Opp'n Br. 18).

Specifically, Simpson cites to section 50.4.2 of chapter 15 of the MBPM, which states:

> FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia,[10] authoritative medical literature and/or accepted standards of medical practice.

(Normand Decl. Ex. A, ECF No. 144-19; Pl.'s Opp'n Br. 18). She also cites to section 13.7.1 of chapter 13 of the MPIM, which states that "[a]cceptance by individual health care providers . . . and limited case studies distributed by sponsors with a financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community." (Normand Decl. Ex. B, ECF No. 144-20; Pl.'s Opp'n Br. 18). Based on these statements, Simpson concludes that an off-label drug use is "reasonable and necessary" only if the major drug compendia "taken together" support that use. (*Id.* at 19-21). Bayer counters that the compendia need not be unanimous—a supportive listing in one major compendium is sufficient for an off-label use to qualify as reasonable and necessary. (Def.'s Br. 15; Def.'s Reply Br. 6-7).

The Court agrees with Bayer. Indeed, the above quoted MBPM language states *only* that a carrier should consider the major drug compendia, and Simpson cites to no binding authority supporting her restrictive reading of that language. Moreover, an off-label drug use is considered

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[10] A "drug compendium" is a database of information concerning drugs, which includes, among other things, approved and unapproved uses. (Compl. ¶ 56 n.6). The Medicaid statute provides that "one or more citations" supporting an off-label drug use in any of the following major drug compendia may establish the medical acceptance of that use: (1) American Hospital Formulary Service Drug Information; (2) United States Pharmacopeia-Drug Information (or its successor publications); and (3) the DRUGDEX Information System. *See* 42 U.S.C. § 1396r-8(k)(6) (referring to subsection (g)(1)(B)(i) of that section).

medically accepted under the Medicaid statute if that use is supported by "*one* or more citations" in the major drug compendia. 42 U.S.C. § 1396r-8(k)(6) (emphasis added); *U.S. ex rel. Worsfold v. Pfizer, Inc.*, No. 09-11522, 2013 WL 6195790, *3 (D. Mass. Nov. 22, 2013) (noting that medical acceptance of an off-label use depends on whether that particular use is included in one of the compendia). It would be anomalous to read the Medicaid and Medicare statutes divergently, finding that an off-label drug use is medically acceptable, and thus compensable, when supported by one compendium under Medicaid but not under Medicare. Accordingly, the Court now assesses whether the Complaint adequately alleges that not a single drug compendium supported the off-label uses of Trasylol that Bayer promoted.

The Complaint generally alleges that each of the major drug compendia does not support the off label uses of Trasylol that Bayer promoted. (*See* Compl. ¶¶ 170-75). With regard to the American Hospital Formulary Service Drug Information compendium, the Complaint alleges that "[n]one of the entries for Trasylol . . . from 1997 through 2007 describe well-supported uses for Trasylol other than the FDA approved indication, on-pump CABG surgery," and that "[o]ther uses of Trasylol are only mentioned as either unproven or with reference to potential adverse effects." (*Id.* at ¶¶ 171-72). With regard to the United States Pharmacopeia-Drug Information compendium, the Complaint alleges that the 1999 and 2000 entries for Trasylol "list[] only repeat CABG surgery and initial CABG surgery in cases of high risk of bleeding as 'Accepted[,]'" and that "[t]he 2001 and 2002 entries list only CABG surgery as 'Accepted.'" (*Id.* at ¶ 173). The Complaint further alleges that, according to that compendium, "[a]ll other uses, including liver transplants, heart transplants, orthopedic surgery, and pediatric surgery, are listed as 'Acceptance not established.'" (*Id.* at ¶ 173). Both aforementioned compendia, according to the Complaint, explicitly state that the "safety and efficacy" of Trasylol for

pediatric use has not been established. (*Id.* at ¶¶ 172, 174). With regard to the DRUGDEX Information System compendium (hereinafter "DRUGDEX"), the Complaint alleges:

> The DRUGDEX entry for Aprotinin [Trasylol] was reviewed and approved by Bayer in 2000. Although this entry lists numerous off-label uses for Trasylol, none of these off-label uses are described as having 'good' documentation that they are both safe and effective, and some, such as orthopedic surgery, are described as 'ineffective.'

(*Id.* at ¶ 175).

Bayer argues that Simpson's allegation concerning the 2000 DRUGDEX entry for Trasylol amounts to an admission that at least some off-label uses of the drug were supported by a major drug compendium. (*See* Def.'s Br. 16). Relatedly, Bayer suggests that that allegation misconstrues the 2000 DRUGDEX entry, and cites to parts of that entry that it considers supportive of the medical acceptance of various off-label uses. (*See id.* at 14-15). For instance, with regard to the off-label use of Trasylol for orthopedic surgery, Bayer points out that although the 2000 DRUGDEX entry describes the efficacy of Trasylol for orthopedic surgery as "ineffective" for adults, that entry simultaneously provides in its summary that Trasylol "[m]ay decrease blood loss and transfusion requirements during and after major orthopedic surgery." (Def.'s Br. 18 n.11; Def.'s Ex. B § 4.5(G)(2), ECF No. 144-6). In response, Simpson cites to various parts of the 2000 DRUGDEX entry that she considers unsupportive of off-label use, and contends that "Bayer's skewed reading of [the 2000 DRUGDEX entry] does not warrant dismissal." (*See* Pl.'s Opp'n Br. 21-22).

Ultimately, for the purpose of resolving this motion, the Court need not determine which off-label uses of Trasylol the 2000 DRUGDEX actually supports. As it stands, Simpson's Complaint does not plausibly allege that the off-label uses of Trasylol that Bayer promoted lacked medical acceptance. This conclusion stems from the Court's inability to reasonably infer

from the Complaint which particular off-label uses of Trasylol the 2000 DRUGDEX entry considers unsupported.

The Complaint specifically alleges that Bayer promoted the off-label use of Trasylol in: (1) valve replacement surgeries; (2) off-pump CABG surgeries; (3) surgeries involving pediatric patients; (4) surgeries involving patients on the antiplatelet drug Plavix; (5) orthopedic surgeries; and (6) liver transplant surgeries. (Compl. ¶¶ 146-52, 157, 164-65). Yet, with regard to the 2000 DRUGDEX entry, the Complaint vaguely alleges that "[a]lthough [that] entry lists numerous off-label uses for Trasylol, none of these off-label uses are described as having 'good' documentation that they are both safe and effective, and some, such as orthopedic surgery, are described as 'ineffective.'" (*Id.* at ¶ 175). It is unclear from this allegation which of the six off-label uses mentioned above are unsupported by the 2000 DRUGDEX entry for Trasylol,[11] and the Court cannot now look to Simpson's Opposition Brief for clarity. *See Commonwealth of Pa ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988) (noting that it is "axiomatic" that a plaintiff may not amend her complaint via her opposition brief). Instead, Simpson must point to specific statements in the 2000 DRUGDEX entry to demonstrate that it does not support each individual off-label use. Without pleading which particular off-label uses are unsupported with specificity, the Court cannot reasonably infer which uses are not "reasonable and necessary" under Medicare.

Alternatively, Simpson suggests that this Court need not consider the DRUGDEX compendium, or any compendia at all, since "doing so . . . ignores the fact (easily inferred from [her] allegations) that the compendia listings themselves are the product of Bayer's misbranding

[11] With regard to the off-label use of Trasylol for orthopedic surgery, the Court finds insufficient support for Simpson's position that DRUGDEX does not support that off-label use. Indeed, Bayer directs this Court's attention to the 2000 DRUGDEX entry's statement that the off-label use of Trasylol for orthopedic surgery "[m]ay decrease blood loss and transfusion requirements during and after major orthopedic surgery." (Def.'s Br. 18 n.11; Def.'s Ex. B § 4.5(G)(2)).

of Trasylol through consistent false and misleading statements, articles, and reports about the drug's safety and efficacy, including off-label uses." (Pl.'s Opp'n Br. 20 (citation omitted)). This suggestion is unavailing, since, as Bayer notes, the Complaint does "not allege[] a single fact regarding what Bayer submitted to the compendia or how the compendia evaluated Trasylol." (Def.'s Reply Br. 8). Instead, Simpson alleges only that "[t]he DRUGDEX entry for Aprotinin [Trasylol] was reviewed and approved by Bayer in 2000." (Compl. ¶ 175). The Court cannot plausibly infer from this statement that DRUGDEX and the other compendia are unreliable because Bayer exerted undue influence, and that, as a result, the Court should ignore them. In any event, it bears mentioning that section 50.4.2 of chapter 15 of the MBPM requires the "consideration of the major drug compendia," and Simpson has not pointed to any qualifications to this language. Accordingly, the Court dismisses Counts VII and VIII of Simpson's Complaint without prejudice.[12]

C. Whether Simpson's State and District of Columbia False Claims Act Causes of Action Survive Dismissal

As discussed above, Simpson brings causes of action under the false claims acts of twenty-one states and the District of Columbia. (*Id.* at ¶¶ 395-537, 545-46). Bayer contends that this Court must dismiss these causes of action as premature because those jurisdictions have not validly declined to intervene. (Def.'s Br. 23-24). On October 16, 2013, John J. Hoffman, the Acting Attorney General for the State of New Jersey, filed a "Joint Notice of Election to Decline Intervention" with this Court. (ECF No. 137). He noted therein that the District of Columbia and every state but Texas had specifically requested that New Jersey notify the Court of their decision to decline intervention. (*See id.*).

[12] Since the Court dismisses Simpson's misbranding causes of action (Counts I through VIII) without prejudice, the Court need not consider Bayer's alternative grounds for dismissal of these causes of action.

Bayer argues that New Jersey's filing did not validly decline intervention on behalf of the states and the District of Columbia for two reasons. (Def.'s Br. 24). First, because that filing does not comply with the specific non-intervention procedures set forth in each jurisdiction's false claims act. (*Id.*). Second, because New Jersey is not a party to this action. (*Id.*). Simpson counters that New Jersey's filing is sufficient since "Bayer does not explain how the filing fails to provide notice." (Pl.'s Opp'n Br. 30). In support, she cites to an unpublished opinion from the District Court for the Southern District of West Virginia that implicitly deemed a similar notice declining intervention acceptable. (*Id.* (citing *U.S. ex rel. May v. Purdue Pharma L.P.*, No. 10-1423, 2012 WL 4056720, *4 (S. D. W. Va. Sept. 14, 2012) *rev'd on other grounds* 737 F.3d 908 (4th Cir. 2013) (implicitly permitting the United States to decline intervention on behalf of California, Georgia, Illinois, New York, and Tennessee))). Simpson further argues that there is no conceivable reason to think that New Jersey misrepresented the requests of the states and the District of Columbia. (*Id.* at 31).

"When interpreting a statute, 'the literal meaning of the statute is the most important, and [courts] are always to read the statute in its ordinary and natural sense.'" *In re Harvard Indus., Inc.*, 568 F.3d 444, 451 (3d Cir. 2009) (quoting *Galloway v. United States*, 492 F.3d 219, 233 (3d Cir. 2007)). Here, each jurisdiction's false claims act requires either the jurisdiction or an official thereof to notify the Court of that jurisdiction's decision to decline intervention.[13] Since

[13] Specifically, the California statute requires the state "Attorney General" to "notify the court that it declines to proceed with the action . . . ." Cal. Gov't Code § 12652(b)(3)(B). The Delaware statute requires the state "Department of Justice" to "[n]otify the court that it declines to take over the action . . . ." 6 Del. C. § 1203(b)(4)(b). The Florida statute requires the state "Department of Financial Services" to "[n]otify the court that it declines to take over the action . . . ." Fla. Stat. Ann. 68.083(6)(b). The Georgia statute requires the state "Attorney General" to "[n]otify the court that it declines to take over the civil action . . . ." Ga. Code Ann. § 49-4-168.2(c)(4)(B). The Hawaii statute requires the "State" to "[n]otify the court that it declines to take over the action . . . ." Haw. Rev. Stat. § 661-25(d). The Illinois statute requires the "State" to "notify the court that it declines to take over the action . . . ." 740 Ill. Comp. Stat. 175/4(b)(4)(B). The Indiana statute provides that "[i]f the attorney general or the inspector general elects not to intervene in the action, the person who initially filed the complaint has the right to prosecute the action." Ind. Code § 5-11-5.5-5(f). The Louisiana statute provides that "[i]f the secretary [of the Department of

this procedure was not complied with here—only the Acting Attorney General of New Jersey notified the Court—the Court grants Bayer's motion to dismiss Counts XIII through XXX, XXXII through XXXIV, and XXXVII. The Court also grants Bayer's motion to dismiss Count XXXI of Simpson's Complaint, her Texas false claims act cause of action, because Texas has not yet declined to intervene in this action. *See* V.T.C.A. Hum. Res. Code § 36.104(a)(2) (requiring the "state" to "notify the court that [it] declines to take over the action" before it may proceed). Since these causes of action are premature, the Court dismisses them without prejudice.[14]

D. Whether Simpson's Remaining Causes of Action are Cabined by Any Applicable Statutes of Limitations

Bayer moves to dismiss Simpson's remaining causes of action, Counts IX through XII and XXXVI, to the extent that they are premised on conduct predating the applicable statute of limitations. (Def.'s Br. 27-29). Counts IX through XII allege, in essence, that because Bayer

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Health and Hospitals, or his authorized designee,] or the attorney general does not intervene, the qui tam plaintiff may proceed with the qui tam action . . . ." La. Rev. Stat. Ann. § 46:439.2(B)(4)(a). The Massachusetts statute requires the state "attorney general" to "notify the court that he declines to take over the action . . . ." Mass. Gen. Laws Ann. ch. 12 § 5C(4). The Michigan statute requires the state "attorney general" to "notify the court and the person initiating the action . . . [t]hat [he] declines to take over the action . . . ." Mich. Comp. Laws Ann. § 400.610a(3)(b). The Montana statute requires the "government attorney . . . to notify the court that [he] declines to take over the action." Mont. Code Ann. § 17-8-406(3). The Nevada statute provides that the state "Attorney General or a designee of the Attorney General pursuant to NRS 357.070" must elect "whether to intervene." Nev. Rev. Stat. Ann. § 357.080(4). The New Hampshire statute requires the "state" to "[n]otify the court that it declines to take over the action . . . ." N. H. Rev. Stat. Ann. § 167:61-c(II)(e)(2). The New Mexico statute requires the state "attorney general" to "notify the court that the state . . . declines to take over the action . . . ." NMSA § 44-9-5(D)(2). The New York statute provides that "[i]f the state declines to participate in the action or to authorize participation by a local government, the qui tam action may proceed . . . ." N. Y. State Fin. Law § 190(2)(f). The Oklahoma statute requires the "state" to "notify the court that it declines to take over the action . . . ." Okla. Stat. Ann. tit. 63 § 5053.2(B)(4)(b). The Rhode Island statute requires the "state" to "[n]otify the court that it declines to take over the action . . . ." R. I. Gen. Laws Ann. § 9-1.1-4(b)(4)(ii). The Tennessee statute requires the "attorney general and reporter" to "[n]otify the court that it declines to proceed with the action . . . ." Tenn. Code Ann. § 4-18-104(b)(3)(B). The Virginia statute requires the "Commonwealth" to "notify the court that it declines to take over the action . . . ." Va. Code Ann. § 8.01-216.5(D). The Wisconsin statute requires the "attorney general" to "[n]otify the court that he or she declines to proceed with the action . . . ." Wis. Stat. Ann. § 20.931(5)(d)(2). Lastly, the District of Columbia statute requires the "Attorney General for the District of Columbia" to "[n]otify the court that he or she declines to take over the action . . . ." D.C. Code § 2-381.03(b)(4)(B).

[14] Because the Court dismisses Simpson's state and District of Columbia false claims act causes of action on this basis, the Court need not consider Bayer's alternative grounds of dismissal for some of these causes of action.

violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), it in turn violated sections 3729(a)(1), (2), and (7) of the FCA by submitting false claims for Medicaid and Medicare reimbursement. (Compl. ¶¶ 366-94). Those Counts allege that Bayer submitted such false reimbursement claims for Trasylol and another one of Bayer's prescription drugs, Avelox. (*Id.*). Count XXXVI alleges that Bayer retaliated against Simpson, in violation of 31 U.S.C. § 3730(h).

In its motion to dismiss these remaining counts, Bayer argues that Simpson "cannot sustain a cause of action under the FCA for Trasylol claims submitted more than six years prior to filing the complaint, on August 5, 2005." (*Id.* at 27). Bayer further argues that Simpson "may not recover for alleged Avelox-related violations that occurred more than six years before she added these allegations—*i.e.*, before July 24, 2006." (*Id.* at 28). Simpson does not refute these arguments. (*See* Pl.'s Opp'n Br. 35-36).

The FCA generally bars relators from bringing "[a] civil action . . . more than 6 years after the date on which the violation of [the FCA] is committed . . . ."[15] 31 U.S.C. § 3731(b)(1). Thus, to the extent that Simpson's remaining causes of action are based on Trasylol-related violations, they may proceed only insofar as they are predicated on violations of the FCA occurring on or after August 5, 1999. In addition, to the extent that Simpson's remaining FCA causes of action are based on Avelox-related violations, they may proceed only insofar as they are predicated on violations of the FCA occurring on or after July 24, 2000. If Simpson chooses to amend her Complaint, the Court instructs her to remove any time-barred allegations.

[15] The three-year tolling period set forth in 31 U.S.C. § 3731(b)(2) applies only when the Government elects to intervene in a *qui tam* action. *See U.S. ex rel. Bauchwitz v. Holloman*, 671 F. Supp. 674, 692-95 (offering a thorough and well-reasoned explanation as to why such is the case). When the Government declines to intervene, the six-year statute of limitations set forth in 31 U.S.C. § 3731(b)(1) applies. *Id.*

IV. CONCLUSION

For the reasons set forth above, the Court **GRANTS** Bayer's motion to dismiss Counts I through VIII, XIII through XXXIV, and XXXVII. In doing so, the Court dismisses those causes of action without prejudice. The Court also instructs Simpson to remove any time barred allegations from Counts IX through XII and XXXVI. Simpson may amend her Complaint within thirty days if she chooses, but may do so only to: (1) allege the existence of a condition of payment from the Government; (2) add allegations concerning the 2000 DRUGDEX entry for Trasylol; and (3) remove time barred allegations from Counts IX through XII and XXXVI.

An appropriate Order accompanies this Opinion.

DATED: 11 of April, 2014.

JOSE L. LINARES
U.S. DISTRICT JUDGE